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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,655	12/21/2001	Jeremy I. Levin	ACY33465-00 D1	5939

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EXAMINER

CHANG, CELIA C

ART UNIT PAPER NUMBER

1625

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,655

Applicant(s)

LEVIN ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,2 and 4-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,2 and 4-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: _____

DETAILED ACTION

1. This application is a divisional of SN 09/492,686. Claim 3 has been canceled. Claims 1-2, 4-6 are pending.

2. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is the scope of claim 4, is it treating diseases or not. The term "inhibiting pathological changes mediated by TNF..." is confusing. Does inhibiting pathological changes referring to future development in the pathological process or does it mean not to have any pathology. If this is diseases being treated, then, the particularity needs to be pointed out i.e. a disease treatable by inhibiting TACE.

3. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method employing the compounds in treating diseases requires inhibition of TACE, does not reasonably provide enablement for the claimed scope which is "mediated" by TNF converting enzyme. Please note that mediate encompassed both inhibit and enhancement. A compound can not simultaneously enhance and inhibits. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to operate the invention commensurate in scope with the claim in performing both enhancement and inhibition function.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutical composition comprising a therapeutic effective amount of a compound, does not reasonably provide enablement for the claimed scope which are drawn to compositions comprising any amount including non-effective or toxic amount.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to operate the invention commensurate in scope with the claim since composition comprising non-effective or toxic amount can not have the described therapeutic utility.

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4. Claims 1-2, 4-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,340,691. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are prima facie obvious variation of the copending claims by one methylene insertion.

Determination of the scope and content of the prior art (MPEP §2141.01)

Claims 1-5 of US 6,340,691 claimed compounds, compositions and method of treating diseases by inhibiting TACE enzyme. Specific compounds of claim 5, particularly col. 77, line 59-60, col. 80, lines 42-47, col. 82 lines 38-44 (see sample structure attached) is very closely related to the instant claims.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Claims 1-5 of US 6,340,691 differ from the instant claims in that instead of one pair of R₈, R₉, R₁₀, R₁₁, forms a ring, R₈, R₉, R₁₀, R₁₁, is optionally a ring. Thus, the difference between the '691 claims and the instant claims is the insertion of one methylene at the R₈, R₉, R₁₀, R₁₁, moieties.

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

Insertion of one methylene chain between a ring and its substituent is normally not patentable because such compounds with or without methylene insertion is expected to have similar activity due to close structural relationship. In re ruddy 121 USPQ 427; Ex parte Nathan 121 USPQ 349; Ex parte Gresham 121 USPQ 422. In the instant case, in the particular TACE inhibitor compounds, the very insertion has been taught to be an optional choice for such compounds (see prior art teaching of col. 3, reciting WO 98/38859, 98/39315, 98/37877) especially in with or without insertion of a methylene chain (see col. 3 lines 24-45 n=1 or 0). One skilled in the art is deemed to be aware of all the pertinent teaching in the art and the explicit teaching of the '691 reference placed the instantly claimed modified compounds in possession of artisan in the field since the modification of known compounds with conventional teaching of attributes for such compounds is prima facie obvious and suggested by the reference.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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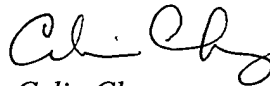
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

OACS/Chang
Feb. 14, 2003


Celia Chang
Primary Examiner
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